

K964517

APR - 1 1997

Summary of Safety and Effectiveness

Linac Scalpel™ Floorstand System

- I. Company:** Surgical Navigation Technologies
530 Compton St.
Broomfield, CO 80020
(303) 439-9709
- II. Product Name:** Linac Scalpel™ Floorstand System
- III.** This submission describes a floorstand based coordinate and fixation system that is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures. The Linac Scalpel™ Floorstand is designed to provide secondary collimation and a fixed isocenter for Radiosurgery or Radiotherapy when used in conjunction with a commercially available Linear Accelerator. The Linac Scalpel™ Floorstand consists of a mechanical structure which is located on the floor at predetermined points and attaches via a gimbal bearing to the head of a linear accelerator. The floorstand is designed to precisely control the accuracy of the collimation during the arcing of the radiation beam from the linear accelerator and the accuracy of the patient position during couch repositioning between arcs.
- IV.** The Linac Scalpel™ Floorstand System was shown to be substantially equivalent to other commercially available patient positioning systems for use in conjunction with linear accelerator -based stereotactic radiosurgery/radiotherapy treatments.